ISLAMIC REPUBLIC OF AFGHANISTAN
MINISTRY OF PUBLIC HEALTH
GENERAL DIRECTORATE OF PHARMACEUTICAL AFFAIRS

# TECHNICAL REPORT

# Waste Management of Pharmaceuticals in Afghanistan


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# Technical Report: Waste Management of Pharmaceuticals in Afghanistan

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## About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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## Key Words

Afghanistan, pharmaceutical supply management (PSM), pharmaceutical waste management, Write-off Disposal Authorization (WODA), supply chain management (SCM)

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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| GAP | Good Accounting Practices |
| GDPA | General Directorate of Pharmaceutical Affairs |
| MoPH | Ministry of Public Health |
| SOP | Standard Operating Procedure |
| SPS | Strengthening Pharmaceutical Systems |
| USAID | US Agency for International Development |
| USD | US dollar |
| WHO | World Health Organization |
| WODA | Write-Off Disposal Authorization |

## ACKNOWLEDGMENTS

This assessment report is a joint product of a wide range of stakeholders concerned of health waste management in Afghanistan. It depicts the waste management situation at present in the country and incorporates the most recent knowledge, experience and insights from the national and international experts in the field.

The report has gone through a series of reviews and edits in a consultative manner. The development of this report began during Dr. Suraya Dalil's tenure as Minister of Public Health. In formulating of this report, many staff members of the Ministry of Public Health (MoPH) at central level including international consultants had jointly supported the process. Subsequently the Core Group comprised of technical persons from General Directorate of pharmaceutical affaires (GDPA), Health legislation implementation ensuring directorate (HLIED) and strengthening pharmaceutical system (SPS) developed a questionnaire and reviewed the reports which existed at that time in order to deepen the understanding of waste management of pharmaceutical products in Afghanistan and other low- and middle-income countries.

The General Director of Pharmaceutical Affairs would like to thank for the contribution of the Core Group for initiating and completing the assessment report of waste management of pharmaceutical products. I am also thrilled to endeavor the implementation of upcoming activities in this important area. Lastly, I would like to express a gratitude to the technical assistance provide by Strengthening Pharmaceutical Systems (SPS) Project, and to the financial assistance of US Agency for International Development (USAID).

**Pharmacist Abdul Hafiz Quraishi**
**General Director of Pharmaceutical Affairs**

The consistent efforts of the following members resulted in the development and finalization of this report—

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Other colleagues and partners who cooperated in development of this report as technical consultants and oversight bodies are—

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## EXECUTIVE SUMMARY

Although Afghanistan already has a pharmaceutical products waste disposal operation, the current operation is generally believed to have many shortfalls—

- The current system of waste disposal is viewed as being substantially dysfunctional.
- The current process timeline is measured in years, giving rise to large stocks of unviable materials that are taking valuable pharmaceutical warehouse storage space but cannot be removed until authorization is received and contributing to inaccurate stock records.
- The volumes of materials being destroyed are seriously misperceived, giving rise to credibility issues in the efficiency and effectiveness of the supply chain and importing.
- Public concerns appear to exist about environmental issues of current destruction procedures.

The Ministry of Public Health (MoPH) is in the process of formulating an appropriate policy and eventual mechanism for the handling of pharmaceutical items requiring destruction.

To better inform and guide the policy development process as to the budgets, range of existing regulations, and the scope of materials and volumes requiring destruction, a study to collate and analyze the data available on pharmaceutical destruction processes and the items scheduled for destruction has been undertaken. A questionnaire relating to waste management of pharmaceutical issues has been developed by a task force of the General Directorate of Pharmaceutical Affairs (GDPA) and used to collect available information at the GDPA and pharmaceutical enterprises.

The collected data from the questionnaires is incomplete and at times confusing and contradictory. However, the data contain enough information to indicate the extent of the problem, to identify key problem areas, and to contribute to debunking some of the more serious misconceptions concerning waste disposal of pharmaceutical products in Afghanistan.

The importance of removing erroneous perceptions on waste disposal of pharmaceutical products needs to be stressed because these perceptions have proved to be pervasive and enduring. If not checked, they have the power to influence major changes to the medicines supply chain, which would be both wastefully costly and significantly detrimental to its effective operation.

In essence, the analysis cannot provide a really good quantitative measurement, because the data are incomplete and confused. But the data are good enough to say what cannot be the case. This is important, because so many misperceptions surround these issues.

The results of the analysis indicate the following—

- Even if the total national pharmaceutical supply to Afghanistan, in its entirety—both public and private sector supplies—were immediately sent to wastage (i.e., 100% wastage), it would still represent (in per capita terms) less than the pharmaceutical wastage generated in the United States and Europe. Afghanistan is simply not buying enough medicine to have a major waste disposal problem from pharmaceuticals.

- The volume of the total annual national estimated waste disposal requirement for pharmaceuticals in the public and private supply chains for Afghanistan is likely to be less than the current domestic garbage collection in the city of Kabul for two hours.

- Even if the entire annual national reported volume of seizures of substandard medicines were to be dumped at one time into the Kabul domestic garbage landfill site (an unlikely event because it would require a convoy of 30 trucks), it would be diluted to less than 1% of the Kabul domestic garbage mix within a week.

- The relative volumes between domestic garbage collection and pharmaceutical waste indicate that disposal of pharmaceutical waste in domestic garbage landfill sites can be an effective disposal method because the pharmaceutical waste will be heavily diluted by the domestic waste.

- Even allowing for price differential in medicines, the potential environmental impact of pharmaceuticals in Afghanistan is still likely to be at least 10 times less than in the United States and Europe on a land area per square kilometer calculation.

- The collected data confirm that no effective systems are operating for any part of the Write-Off Disposal Authorization (WODA) process. That is the process of formally accounting for the removal of the stock from inventory and financial records and authorizing its destruction. This situation needs to be addressed.

Concerns arise because—

- The lack of a clear WODA procedure means that stocks scheduled for destruction must be held for an inordinate length of time—typically reported as in excess of a year—until final authorization can be achieved for their destruction. These stocks are occupying badly needed warehouse space and thereby reducing the flow capacity of the main medicine supply.

- Although volumes are not likely to be high, danger can arise if disposal is not correctly managed and damaged, used, or expired products can find their way back into the marketplace. Practically, ensuring products for disposal cannot be reused is a very easy process, but without adequate written procedures and monitoring oversight an element of risk exists.

Overall conclusions are as follows—

- The volume of pharmaceutical waste currently being generated is not of a high enough volume to create a significant environmental or waste management problem.

- The lack of clear WODA procedures means that long delays occur in obtaining the necessary authorizations for product destruction, which adversely affects the flow of the main medicine supply. Moreover uncertain regarding destruction brings a risk of possible product reuse.

- It is strongly recommended that detailed WODA procedures for pharmaceutical products be developed and implemented and that in the implementation process consideration be given to reducing misconceptions and erroneous perceptions of pharmaceutical waste volumes.

# INTRODUCTION

## Background

Afghanistan already has a pharmaceutical product waste disposal operation, and pharmaceutical materials are reviewed for disposal and destruction, but the current operation is generally believed to have many shortfalls—

- The current system of waste disposal is viewed as being substantial dysfunctional.
- The current process timeline is measured in years, giving rise to large stocks of unviable materials that are taking valuable pharmaceutical warehouse storage space but that cannot be removed until authorization is received, thus contributing to inaccurate stock records.
- Perceptions of the volumes of materials being destroyed appear to be seriously inaccurate, giving rise to credibility issues in the efficiency and effectiveness of the supply chain and importing.
- Public concerns exist about environmental issues of current destruction procedures.

Attempts at estimating the scale of the issue using total throughput volumes of pharmaceuticals have indicated no major issue on waste disposal because not enough volume of pharmaceuticals is being procured for the public sector in Afghanistan for a major issue on waste disposal to arise. However, in the face of persistent perceptions of a major problem in waste management, a task force has been formed within the MoPH to try to quantify the extent of any problem and formulate an evidence-based approach for future waste management of pharmaceutical items.

## Objective

The MoPH is in the process of formulating an appropriate policy and eventual mechanism for the handling of pharmaceutical items requiring destruction.

To better inform and guide the policy development process as to the budgets, range of existing regulations, and scope of materials and volumes requiring destruction, the GDPA desires to collate the information currently available on the destruction process and pharmaceutical products scheduled for destruction.

The overall objective is to collate and analyze the available data on pharmaceutical destruction processes and the items scheduled for destruction to identify any shortfalls in the existing policies and regulations and to formulate estimates of the volume and content of the pharmaceutical items requiring destruction. It is recognized that the current data may be incomplete and can probably be used only for general guidance, but even this can serve a useful purpose.

## Purpose and Goal

The overall purpose of this technical report is to present an analysis of the data collected relating to the waste disposal of pharmaceutical products within the public sector in Afghanistan and to use that analysis to inform and develop future options for addressing waste management of pharmaceutical product issues.

This report's goal is to deliver—

- An analysis of the collected data on waste management of pharmaceutical products in the public sector in Afghanistan and an assessment of the scale and extent of the issues relating to waste management of pharmaceuticals
- Possible scenarios to address waste management of pharmaceutical items
- A methodology for stakeholder involvement in the process of developing practical approaches and operational guidelines for waste management of pharmaceuticals

## Scope of the Study

A survey of activities relating to pharmaceutical waste management has been undertaken at the GDPA, Pharmaceutical enterprises and other authorities and estimates on throughput volumes have been undertaken.

## Overall Approach

A questionnaire relating to waste management of pharmaceutical issues has been developed by the task force and applied at the GDPA and pharmaceutical enterprises.

The overall aims of the questionnaire are to gather date to determine—

- If potentially unsafe pharmaceutical products are being effectively removed from public and patient access and destroyed
- If an accurate accounting of the process exists that complies with Good Accounting Practices (GAP) and that all necessary records reflect the process in an open and transparent way
- If pharmaceutical products are being destroyed in an environmentally sound way
- If competent/regulatory authorities are aware of the volumes of disposals being undertaken so they can undertake remedial management action to reduce potential future disposal volumes

Annex 1 contains the questionnaire developed.

## Methods Used

The questionnaire was administered by a team of data collectors from the MoPH and implementing partners who were all familiar with the practicalities of pharmaceutical management within the public sector in Afghanistan.

Data collection was by discussion with the implementing department, and comprehensive briefing notes were produced for the data collectors to follow.

### *Planning Guidance for Data Collectors*

- Discuss this briefing note and draft questionnaire with the responsible MoPH/GDPA personnel and seek to actively engage them in the process.

- Use the guidelines and other documents related to procurement and distribution of the intended data collation activities to complete the proposed questionnaire (on their own) for their own pharmaceutical supply.

- Agree with MoPH/GDPA staff to determine which departments are involved in handling data for pharmaceutical items for destruction, where the data are located, and the extent of the data available.

- Clearly identify the departments that need to be visited and that do they have data available. Then obtain the necessary permissions to access the available data and work with the departmental staff.

### *Preparations before Visiting the Identified Units*

- Notify the unit of your proposed activities.

- Contact the unit to explain your proposed activities and provide a copy of the questionnaire.

- Agree a time to visit the unit and the data collection activities.

### *Guidance for Data Collectors on Implementing Questionnaire*

During the visit to the unit, the data compilation officers should ensure that—

- They take time to explain to the unit officer what they are doing and why

- They stress they are not part of an audit team and are not there to measure the performance of the unit—only to collect data to help estimate future volumes

- The focus of their visit is on the data collection (The should not try to make comments or observations on the data at this stage, but wait for the analysis.)

- Unit staff are treated as equal partners in the search for clarity and resolution and they are asked for their opinions and inputs

- If the data are incomplete or confused, they do not try to criticize or even imply criticism (Explain to the unit's staff that we want the best estimate of its accuracy and completeness, so that we can see how it can be used to guide the future policy development.)

## Limitations of the Data/Information

From the outset, it was recognized that the currently available data may be incomplete, but it was hoped that it would prove adequate to confirm theoretical calculations on the potential volume of waste pharmaceutical materials being generated and that it could be used for general guidance in developing future policy and procedure.

## RESULTS OF COLLECTED DATA

### General

As expected, the data are incomplete and at times confusing and contradictory. However, the data contain enough information to act as an indication of the extent of the defects. The completed data collection questionnaires are contained in Annex 2.

**Table 1. Overview of Results**

| Questionnaire section | Summary responses |
|---|---|
| A. Why are items scheduled for destruction | No clear documentation or system exists to record reasons, currently it is impossible to know if major source is date expiry or product quality assurance failure. |
| B. Volumes schedule for destruction | No clear documentation or system exists to record values or volumes, but some information is available and some estimates are made by visual inspections. |
| C. Contents of scheduled items for destruction | No clear system exists to record categories, but some medicine names are recorded. |
| D. Cost of items to be destroyed | Some estimates are available for cost of destroyed medicines, but systematic recording or calculating of values is not undertaken. |
| E. WODA policy | High-level policy exists but is incomplete and unclear. |
| F. WODA regulation | Highly confused responses were given, citing Medicine Law as a regulation, but no real procedures were found. |

### Key Results

**Table 2. Volumes and Values of Items Scheduled for Destruction, Last 12 Months**

| Unit | Items | Weight (metric tons) | Volume (cubic meters) | Value (USD) | Major item |
|---|---|---|---|---|---|
| Pharmaceutical establishment | 406 | 18 | NA | 44,830 | Aspirin tablets |
| Production and Import Monitoring Department | 109 | NA | NA | 6,000[a] | Paracetamol syrup |

Note: NA = not available
a. Estimated only, no measurement or collation in place.

**Table 3. Destruction**

| Unit | Prime source of items | Potential environmental hazard items | WODA procedure | Destruction procedure | Destruction method |
|---|---|---|---|---|---|
| Pharmaceutical establishments | Private sector | Depo-Provera but only 100 vials, too small to have environmental impact | None | | Burning |
| Production and Import Monitoring Department | Private sector | None | | | |

# ANALYSIS

Even though the collected data are clearly incomplete, they contain enough information to identify key problem areas and to contribute to debunking some of the more serious erroneous misconceptions concerning waste disposal of pharmaceutical products in Afghanistan.

The importance of removing erroneous perceptions about waste disposal of pharmaceutical products needs to be stressed because these perceptions have proved to be pervasive and enduring and—if not checked—have the power to influence major changes to the medicine supply chain, which would be both wastefully costly and significantly detrimental to its effective operation.

In undertaking this analysis, stating what cannot possibly be the case is as important as stating what may be the case. The data are not really good enough to construct a hard evidence-based, quantitative, accurate, situation assessment, but the data are good enough to state what cannot possibly be the case and thereby serve to debunk some of the wilder misconceptions.

In formulating the following debunking section, data have been drawn from a number of sources, usually to provide a comparison with the situation in Afghanistan.

## Situation in Perspective: Values and Volumes of Pharmaceutical Waste

The current volume of pharmaceutical products being destroyed in Afghanistan is not accurately known. However, some reasonable indications exist, and the scale of the problem is such that even if the actual volume of pharmaceutical waste being generated in Afghanistan were 10 times higher than the estimated quantities, it does not make a significant difference to the overall conclusions:

The total public sector supply of medicines in Afghanistan is estimated at about USD 60 million annually (including nongovernmental organization and donor supplies), and the private sector adds a further USD 140 million annually.[1]

Information from the essential medicines Basic Package of Health Services / Essential Package of Hospital Services supply operation, managed by US Agency for International Development (USAID)-funded Strengthening for Pharmaceutical Services (SPS) program, is reliably known: During the period from April 2007 until December 2010, the volume of pharmaceutical material for disposal amounted to approximately USD 300,000 in value, about 40 cubic meters in size, that is, equivalent to about four, standard US hospital 10-yard dumpster containers. The bulk of the pharmaceutical component was magnesium sulfate beyond its expiration date.

A waste disposal rate of around 4% by value of supply is within the accepted limits of 3% to 5%.[2]

[1] GDPA in National Medicine Policy 2014 ¶ 1.2.

Even if a rate of 10% disposal for the Afghanistan medicine supply is assumed, for the total combined public and private sector—and such a high rate is unlikely to be possible without being massive disposal stockpiles being well known—the total annual disposal requirement for the entire country (public and private sectors combined) would be around USD 20 million annually, with an approximate volume of 270 standard US hospital 10-yard dumpsters, equivalent to about 100 metric tons per year.

To put these volumes in perspective, they can be considered on a per capita basis (table 4).

**Table 4. Cost Comparison of Pharmaceutical Waste Volumes**

| Country | National medicine supply (USD millions) | Wastage rate by value (%) | Value of pharmaceutical waste (USD millions) | Value of waste per capita (USD) | Volume of waste (metric tons) | Volume per capita (grams) |
|---|---|---|---|---|---|---|
| Afghanistan | 200 | 10 | 20 | 0.67 | 100 | 3.3 |
| United States | 297,358 | 1 | 2,974 | 9.5 | 14,870 | 47.4 |
| Germany | 51,414 | 1 | 514 | 6.3 | 2,570 | 31.3 |

*Medicines supply data from:* OECD (2011), "Pharmaceutical expenditure," in *Health at a Glance 2011: OECD Indicators;* OECD Publishing (accessed at http://apps.who.int/medicinedocs/documents/s19848en/s19848en.pdf).

If the total national pharmaceutical supply to Afghanistan, in its entirety for both public and private sectors, were immediately sent to wastage (i.e., 100% waste), it would still only represent (in per capita terms), less than the pharmaceutical waste generated in the United States.

Afghanistan is simply not buying enough medicine to create a major waste disposal problem from pharmaceuticals.

## Situation in Perspective: Other Wastes

The domestic waste production from Kabul alone is reported by UN-Habitat as 3,000 metric tons per day, with a collection capacity of only 400 metric tons per day. The total annual national estimated waste disposal requirement for public and private supply chain pharmaceuticals for Afghanistan is likely to be less than the current domestic garbage collection in Kabul in two hours.

The bulk of the pharmaceutical materials currently being generated for destruction is generally believed to arise mainly from substandard and counterfeit medicines being seized by MoPH personal from the marketplace and importation points rather than from the public and private sector pharmaceutical supply chain. This is reported (somewhat improbably, since it would require a storage volume of around four times the current total storage capacity of the Central Medical Stores) as 300 metric tons in 2008. However, even if this figure is correct, it would still represent only one day's waste collection for Kabul.

[2] Management Sciences for Health. *MDS-3: Management Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health; 2012, chap. 40.1. http://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies

Even allowing for gross inaccuracies in these estimates, the compelling conclusion must be that pharmaceutical waste is only a tiny fraction of the domestic waste being collected in the country. This conclusion is important for two main reasons—

- It helps provide perspective on the volume of the problem.

- It provides a supporting base for the safe disposal of pharmaceutical waste in municipal domestic waste tips or landfill sites, since it pharmaceutical waste can clearly be heavily diluted by domestic waste.

In effect, even if the entire annual reported volume of national seizures of substandard medicines were to be dumped at one time into the Kabul landfill site ( an unlikely event that would require a convoy of 30 trucks), it would be diluted to less than 1% of the Kabul domestic garbage mix within seven days.

## Situation in Perspective: Potential Environmental Impact

The current annual total medicine supply has been estimated by GDPA as USD 200 million in value, which is equivalent to about the same consumption volume as 10 district hospitals in Europe or the United States, probably about the same as a small city.

However, medicine supply in Afghanistan is distributed throughout the country. In crude terms, Afghanistan has an area of around 650,000 square kilometers, thus USD 310 of medicine consumption per square kilometer. In contrast, the United States has a projected medicine expenditure of more than USD 300 billion (2012) equating to medicine consumption of USD 30,500 per square kilometer.

Even allowing for price differential in medicines, the potential environmental impact of pharmaceuticals in Afghanistan is likely to be at least 10 times less than in the United States or Europe. Afghanistan is simply not providing enough medicines to create significant environmental impact from pharmaceuticals.

Although individual areas of concentration are always a possibility and need to be managed, at the current and envisioned future levels of pharmaceutical supply, the overall potential environmental burden of pharmaceuticals must be considered to be far less than in Europe or North America.

In general, for waste disposal of pharmaceuticals, three main categories of environmental concern are recognized—

- Antineoplastic/cytotoxic preparations, mainly used during cancer therapies. These have only a very small use in Afghanistan and only at major hospitals and specialist centers.

- Poisons (medicines that have a major impact at low levels and/or have cumulative effects in the body, e.g., heavy metals). These are now very little used, and none are contained in the national essential medicines list.

- Hormonal contraceptives (because of their very high volume/use rate). Hormonal contraceptive prevalence rate (effectively, the percentage of women of reproductive age who use a modern method of contraception) in Afghanistan remains low, well below 20%.

In overall terms, the predicted environmental impact of pharmaceutical waste must be considered as being very low.

## Collected Data: Volumes

The collected data show that only small volumes of pharmaceutical waste are currently being managed. At a combined total of perhaps 75 metric tons, the operation is almost certainly not capturing all products, and the data must be considered incomplete.

## Collected Data: Systems

The collected data show that no effective systems are in operation for any part of the WODA process and that this situation needs to be addressed.

Some general policy statements on waste and disposal of pharmaceutical products exist, but clearly a need exists for detailed and transparent procedures. This lack is especially worrying for two reasons—

- The lack of a clear WODA procedure means that stocks scheduled for destruction must be held for an inordinate length of time—typically reported as in excess of one years—until final authorization can be achieved for their destruction. These stocks are occupying badly needed warehouse space and thereby reducing the flow capacity of the main medicine supply system.

- Although volumes are not likely to be high, a danger does exist that if disposal is not correctly managed, then damaged, used, or expired products can find their way back into the marketplace. Practically, ensuring that products for disposal cannot be reused is very easy, but without adequate written procedures and monitoring oversight a significant risk element arises.

## Overall Conclusions

- A high enough volume of pharmaceutical waste is not currently being generated to create a significant environmental or waste management problem.

- The lack of clear WODA procedures means long delays occur in obtaining the necessary authorizations for product destruction, which adversely affects the flow of the main medicine supply and creates uncertainty regarding destruction, thus bringing a risk of possible product reuse.

- Full formal written WODA procedures need to be developed and implemented.

## DISCUSSION AND RECOMMENDATIONS

### Defining the Range of Products

The situation on clinical waste is always far, far more serious than on pharmaceutical waste—both in terms of volumes and technical complexity. It is a regrettable fact that any activities, and more especially any facilities, that are provided for pharmaceutical waste are often "hijacked" and become completely overwhelmed by clinical waste issues. It is essential that from the outset in addressing pharmaceutical waste all active parties clearly understand that clinical waste is an entirely different undertaking in terms of both volume and technical approach to disposal and cannot effectively be addressed through pharmaceutical waste management operations.

### Managing Erroneous Perceptions and Expectations

A key requirement in addressing waste disposal of pharmaceuticals in a low-income-country environment is to manage perceptions and expectations.

Currently, Afghanistan is simply not using enough medicines (still less than USD 1 per capita public sector supply, compared with USD 400+ per capita for high-income countries) to create a major pharmaceutical disposal problem. However, in Afghanistan, as in nearly all low-income countries, deep-rooted and hard-to-remove perceptions exist of huge wastage of pharmaceuticals.

In reality, waste from expired and damaged medicines is rarely more than 10% in any of the world's countries, and although reducing waste is always a good thing, the perception of huge waste usually stems from serious misunderstandings.

Although accurate data are not available for Afghanistan, reports indicate that the bulk of pharmaceutical items destined for destruction arise from seized substandard and counterfeit products. Greater import regulatory control is required to reduce the size of this problem, which must be considered a long-term development, linked to overall medicine quality assurance issues. However, destruction of substandard products from the marketplace should be viewed as a positive activity of improving overall medicine quality, rather than as a waste-generation problem.

For the public sector people need to recognize that a well-designed and operated medicine supply system is supposed to have a small degree of waste. Indeed, if no waste occurs, almost certainly life and well-being are being sacrificed for bureaucracy. The essence of effective supply is that critical medicines are available when needed. Ensuring they are available means holding contingency stocks, and such supplies can give rise to medicine expiry.

For example, the human cost of not having anti-snake serum available is often loss of a life. It is a critical item. So the system must ensure enough serum is available. It is certain that some is going to expire before it can be used and will need destruction. This "waste" is deliberately designed into the supply system. Zero-wastage systems should never exist, because a consequence of contingency stock holding is nearly always a small degree of expired products.

In formulating the development of detailed WODA procedures, the need to manage perceptions and expectations should be taken into account—and that probably requires a degree of explanation and reasoning that would normally be included in procedural manuals.

## Development of WODA Procedures

WODA is the acronym given to the process of write-off and disposal authorization and eventual physical destruction of pharmaceutical products.

The key aims of WODA are as follows—

- Ensure that potentially unsafe pharmaceutical products are removed from public and patient access and destroyed
- Ensure that an accurate accounting of the process is undertaken to comply with GAP and that all necessary records reflect the process in an open and transparent way
- Ensure that pharmaceutical products are destroyed in an environmentally sound way
- Alert competent/regulatory authorities to the volumes of disposals being undertaken so they can undertake remedial management action to reduce potential future disposal volumes

Essentially, the WODA process consists of four parts with the following key aims—

- Pharmacy Technical Function: This function involves certification that a particular pharmaceutical product is not viable for human use (damaged, date expired, substandard, unsafe for human use, unregistered). Sometimes this function may involve condemning seized or confiscated items.
    - Often this status will be obvious (e.g., out-of-date product), but in some cases it may be necessary to assemble a panel of experts to adjudicate on a complex technical quality point, or if there has been a legal challenge to a seizure or confiscation.
- Financial Function: This is the accounting function of authorizing the removal of nonviable stock and its corresponding value from inventory.
    - Often this action will be straightforward, and the declared value of the material will be provable from audit trail records, but in some cases it may be necessary to screen for abuse of tax rebates for destroyed stock, which have declared inflated values for the materials.
- Management Function: This is the destruction function of ensuring that the pharmaceutical materials are destroyed in an environmentally sound manner that precludes the possibility of their being reintroduced into the supply chain or to human access. This function often requires a major supervision element to ensure procedures are followed.

  - Appropriate destruction methods will not to be decided on for the envisioned volumes of materials, balancing cost with effectiveness and environmental factors, and an appropriate supervision method will need to be developed to ensure determined methods are implemented.

- Feedback Function: This function involves notifying the competent/regulatory authorities of any unusual or high disposal volumes so they can address potential quality issues or supply chain management shortfalls.

  - It will be necessary to formulate a feedback mechanism that can highlight potential genuine problem areas without overstating normal levels of waste inherent in any medical supply chain.

### *Proposed Mechanism for Formulating WODA Procedures*

A task force of key players should be assembled. It will be important that this task force include key stakeholders, including the private sector.

Initially, the task force should be under the leadership of the MoPH's General Directorate of Pharmaceutical Affairs.

After the task force develops its approved terms of reference and action plan and appoints a chairperson and other officers, it will receive official empowerment and authorization from the MoPH to undertake its tasks.

The task force would be expected to—

- Review the current WODA situation for pharmaceuticals in Afghanistan and identify strengths, weaknesses, and gaps.

- Consult with various specialist advisers and experts on the identified issues.

- Consider the realities of the volumes of materials involved, the cost factors, the technical and environmental aspects, and the practicalities of operations—especially in remote and rural areas, and the need to observe GAP, transparency, and openness.

- Formulate an initial draft WODA policy document, which will be subject to consultation among specialist parties.

- Compile a final draft WODA policy document that will be presented to the MoPH for consideration and review and eventual approval.

- Compile Standard Operating Procedures (SOPs) for WODA operations focusing heavily on the practicality of operations and the cost elements.

- Offer the SOPs for review by those parties with the responsibility for implementation, and in the light of the feedback received prepare final versions that will be presented to the MoPH for consideration and review and eventual approval.

## *Key Considerations in Formulating the WODA Procedures*

The following considerations should guide development of procedures—

- Recognize the size of the total national medicines supply
- Recognize the size of the pharmaceutical waste being generated
- Recognize the administrative cost and impacts in the supply chain

Any WODA procedure must be simple enough to operate quickly and at very low administrative cost.

For example, within the public sector, authority for destruction could be decentralized and delegated to local bodies on a tiered value system:

- Less than USD 50,000, any one medical officer with one registered pharmacist
- USD 50 to 100,000, three people consisting of any combination of medical officers and pharmacists
- USD 500,000, five people consisting of any combination medical officers and pharmacists
- Above USD 500,000 deputy minster or minister

Not more than five (as an absolute maximum) signatures should be required to authorize stock destruction.

Physical destruction of products to prevent reuse can be as simple as dousing in crude fuel oil or waste sump oil. This will ensure no possibility they can be reused before they are disposed of at a landfill site.

## *Managing Perceptions and Expectations*

A specific SOP for handling antineoplastic and cytotoxic preparations can be included in the WODA procedures manual. Such a requirement is not really necessary given the current very low volumes of these preparations in use, but it will help manage perceptions by providing assurances that the "really dangerous" products have been seriously considered and are being addressed.

Produce a guidance document for WODA in the private sector based on the public sector SOPs, and disseminate it widely. This should assist in dispelling some of the current misconceptions about the volumes of pharmaceutical waste being produced, By helping to capture the volumes being destroyed, it will provide an accurate picture of the true value of pharmaceutical waste being generated.

## Possible WODA Scenarios

### *Authorization of Destruction and Witnessing of Physical Destruction*

The private sector is highly unlikely to accept responsibility for implementing a bureaucratically complex authorization procedure or an expensive physical destruction method.

Engaging local or regional pharmaceutical bodies in the authorization and witnessing of destruction methods would provide a flexible and easily administered solution, and with the boost of professional recognition of maintaining environmental safety, private sector firms may be more motivated to follow disposal procedures.

### *Disposal Procedures*

Prevent reuse by despoiling with waste oil, fuel oil, or drenching in water. This is a cheap and effective method of rendering the product unsuitable for resale.

Disposal to a landfill site by mixing with domestic garbage provides a cheap and easy disposal method for current pharmaceutical waste volumes.

### *Incineration*

The World Health Organization (WHO) recommends that if pharmaceutical waste is to be incinerated it should be at temperatures above 1,200 °C and has estimated the cost of commercial incineration at between USD 2.2 and 4.1 per kilogram.[3] For Afghanistan this would equate to an annual cost of about USD 300,000 per year, around 0.15% of the medicine acquisition cost of currently estimated pharmaceutical waste volumes.

Although a full feasibility study is probably required to definitively determine the viability of incineration of pharmaceutical waste in Afghanistan, the indications are that in the short to medium term, incineration should only be considered as a purchased service, if and when a suitable commercially operated incinerator becomes available in Afghanistan. Operation of such technically complex equipment with the limited resources currently available, and ensuring full compliance with environmental protection regulations, appears inappropriate for the MoPH at this time.

#### *Low-Cost Incineration*

The smallest De Montford medical incinerator, which was designed as a low-cost incinerator for low-income countries conforming to WHO 2005 guidelines, handles 12 kilograms per hour. Their normal use is at hospital level.

Operation of these incinerators has proven problematical, and in recent surveys few were operating well enough to avoid environmental problems. The overall conclusion is that unless strong oversight and firm human resource management are in place, then the excellent technical aspects of the incinerator can be negated and its value much reduced.

[3] The following materials in this section are drawn from WHO: Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies.

At least four of these incinerators would be required to handle the entire national pharmaceutical waste supply.

*"Small-scale low cost incinerators will not meet modern emission standards for many pollutants, e.g., carbon monoxide, particulate matter, dioxin/furans, hydrogen chloride, and possibly several toxic metals. To meet emission standards, incinerators must be designed to use air pollution control equipment (removing particles, acid gases, etc.), combustion process monitoring (temperature, flow rates, etc.), and process controls (waste, fuel, air flows). Few of these technologies are adaptable to small-scale low cost incinerators that do not have exhaust fans, pollution controls, dampers, monitoring, electrical power, etc. These technologies will greatly increase the cost and complexity of incinerators, and they are unlikely to perform reliability in many settings given the need for careful operation, regular maintenance, and skilled operators."*

### *Buying a Commercial Incinerator*

*"Based on the estimated potential pharmaceutical waste of 200 tons per year, an engine with a minimum capacity of 1000 kg per day is required (1 year = 52 weeks @ 5 days). If a cycle is about six to eight hours, than two cycles are needed per day. The initial investment of this type of incinerator is roughly USD 50,000. Other cost, such as cost for land, cost for building, fuel cost, labor cost, and other operating cost can be estimate about USD 73,500 per year. Indirect cost such as training cost, uniforms and safety equipment cost, ash disposal costs, and waste collection trucks should also take into consideration."*

## CONCLUSION

Although the calculated volume of pharmaceutical waste currently being generated in Afghanistan is not considered large enough to cause significant problems of environmental impact and waste management, the WODA process needs to be addressed to ensure adequate documentation and implementation of formalized procedures.

It is strongly recommended that detailed WODA procedures for pharmaceutical products be developed and implemented.

## ANNEX 1. DATA-GATHERING QUESTIONNAIRE

# GOVERNMENT OF AFGHANISTAN
# MINISTRY OF PUBLIC HEALTH

### GENERAL DIRECTORATE FOR PHARMACEUTICAL AFFAIRS
### DATA COLLECTION OF PHARMACEUTICAL ITEMS SCHEDULED FOR DESTRUCTION

**Objectives of the Data Collation of Pharmaceutical Items Scheduled for Destruction**

The MoPH is in the process of formulating an appropriate policy and eventual mechanism for the handling of pharmaceutical items requiring destruction.

In order to better inform and guide the policy development process as to the budgets, range of existing regulations, and the scope of materials and volumes requiring destruction, the GDPA is desirous of collating the information which is currently available on the destruction process and pharmaceutical products scheduled for destruction.

The overall objective is to collate and analyze the data which is available on pharmaceutical destruction processes and the items scheduled for destruction so as to identify any shortfalls in the existing policies and regulations and to formulate estimates of the volume and content of the pharmaceutical items requiring destruction. It is recognized that the current data may be incomplete and can probably be used only for general guidance, but even this can serve a useful purpose.

**Planning Guidance for Data Collectors**

Discuss this briefing note and draft questionnaire with the MoPH/GDPA, and seek to actively engage them in the process.

Advise the CPDS of the intended data collation activities and invite any of their members to also complete the proposed questionnaire (on their own) for their own pharmaceutical supply.

Work with MoPH/GDPA staff to determine, which departments are involved in handling data for pharmaceutical items for destruction; where the data is located; and the extent of the data available.

Clearly identify the departments which need to be visited; contact them to confirm that they have data available; and then obtain the necessary permissions to access the available data and work with the departmental staff.

**Preparations before Visiting the Identified Units**

***Notify the Unit of your proposed activities***
Contact the unit(s) to explain your proposed activities and provide a copy of the questionnaire.

Agree a time to visit the unit and the data collection activities.

**Guidance for Data Collectors – Implementing Questionnaire**

During the visit to the Unit, the Data Compilation Officer(s) should ensure that:

- They take time to explain to the Unit Officer what they are doing and why.
- Explain that they are NOT part of an audit team. They are NOT there to measure the performance of the unit – only to collect data to help estimate future volumes.
- The focus of their visit is on the data collection—do not try to make comments or observations on the data at this stage—wait for the analysis.
- Unit staff should be treated as equal partners in the search for clarity and resolution; ask for their opinions and inputs.
- If the data are incomplete or confused do NOT try to criticize or even imply criticism—explain to the units staff that we want the best estimate of its accuracy and completeness, so that we can see how it can be used to guide the future policy development.

## PHARMACEUTICAL ITEMS FOR DESTRUCTION DATA COMPILATION QUESTIONNAIRE

1. **DATE OF DATA COLLECTION:**

2. **NAMES OF DATA COLLECTORS:**

3. **NAMES AND TITLES OF PERSONS IN UNIT VISITED:**

ADVICE FOR DATA COLLECTORS:

**Data Source:**

It is expected that the two main sources will be GDPA's inspection of production unit and Health legislation and implementation ensuring Dep. (HLIED).

For Each Data Source, try to complete a separate, full questionnaire, which follows.

Use one questionnaire for GDPA and another copy for HLIED

Discuss with the staff involved in processing the disposal/destruction the requests they receive:

How accurate the staff feel the data is—e.g., they think the prices, volumes are reasonable and all departments report—or only a few departments report and they only guess the prices.

Make an estimate of how confident are you with the data to write a report.

| SECTION | | QUESTIONS | | | |
|---|---|---|---|---|---|
| **A WHY are the items scheduled for destruction** | A1 | Try to collect data on the volume of the items scheduled for destruction by each reason, by either value (Afghani/USD) or volume (cu m) or by number of line items | | | |
| | A 2 | Is there a system to document the reasons of destruction of the pharmaceuticals? Yes / No | | | |
| | A 3 | Is there a system to document the reasons and value, volume or line items of the pharmaceuticals for destruction? Yes / No | | | |
| | A4 | Measured by: State: Value, Volume, Line Item count | | | |
| | A5 | Time Period: (e.g., last year) | | | |
| | | **Reason State documented not documented and why not documented** | **Value** | **Volume** | **Line item** |
| | A6 | Date expired | | | |
| | A7 | Damaged | | | |
| | A8 | Failed quality control testing | | | |
| | A9 | Confiscated, unlicensed medicine | | | |
| | A10 | Confiscated prohibited import | | | |
| | A11 | Suspected counterfeit | | | |
| | A12 | Excess to requirements (expired) | | | |
| | A13 | Other substandard | | | |
| | A14 | Other causes, specify: | | | |
| **B VOLUME express as cubic meters or metric tons** | | Of the items scheduled for destruction: | | | |
| | B15 | How many line items (individual pharmaceutical preparations items) are present? | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | B16 | What is the estimated volume of items for destruction (cubic meters or metric tons) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | B17 | Which item represents the largest volume (cubic meters or metric tons) State item: (e.g., paracetamol 500 mg) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | B18 | State volume (cubic meters or tons) of the item mentioned above | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| **C CONTENT** | C19 | Record the volume or weight of **nonmedicine** items (nonmedicine = condoms, gloves, dressings, etc.) by volume (cubic meters or weight including packing materials) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | C20 | Record the volume or weight of the pharmaceutical **liquids** (includes syrups, injectable and IV fluids) to solids by volume (cubic meters or weight, e.g., 10% liquids by cubic meters) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | C21 | Are there any antineoplastic/cytotoxic preparations present? Yes / No | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | C22 | Are there any hormonal contraceptives present? Yes / No | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | C23 | Are there any Fixed-Dose Combination (FDC) preparations for TB, malaria, or HIV present? Yes / No | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |

| SECTION | | QUESTIONS | |
|---|---|---|---|
| **D COSTS express as Afghani or USD** | D24 | What is the estimated value of items for destruction (Afghani or USD)? | |
| | | Last 3 months | Last 12 months |
| | | | |
| | D25 | Which one pharmaceutical line item represents the largest cost? state item | |
| | | Last 3 months | Last 12 months |
| | | | |
| | D26 | State value of this one largest item (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | | |
| | D27 | What is the total cost of the nonmedicine items present? (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | | |
| | D28 | What is the largest source by cost of the items? e.g., USAID, CMS, UNFPA, etc. | |
| | | Last 3 months | Last 12 months |
| | | | |
| **E Existing policy for Write-Off, Disposal, and Destruction of pharmaceutical products** | E29 | Is there a formal written **POLICY** for the **write-off disposal** of pharmaceutical items. Yes / No<br><br>If Yes, try to determine the source: GDPA/MoPH/HLIED, etc.<br>State source:<br><br>and try to obtain a copy of the document<br><br>If a copy is not available try to record key points:<br><br>• who can authorize<br>• number of authorities (signatures) required<br>• value limits<br>• Single value limit and what is the value:<br>• Multiple tiered values:<br>• Tier 1 value and number of signatures required:<br>• Tier 2 value and number of signatures required:<br>• Tier 3 value and number of signatures required: | |
| | E30 | Is there a formal written **POLICY for the physical destruction** of pharmaceutical items? Yes / No<br><br>If Yes, try to determine the source GDPA/MoPH/HLIED, etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime disposal methodology: bury/burn/landfill<br><br>State method. | |

| SECTION | | QUESTIONS | |
|---|---|---|---|
| **F**<br>**Existing regulations for WODA (write-off, disposal, and destruction) of pharmaceutical products** | F31 | Is there a formal written REGULATION/PROCEDURE for the write-off disposal of pharmaceutical items? Yes / No | |
| | F32 | IF **YES**, try to determine the source: GDPA/MoPH/HLIED etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>IF a copy is not available<br><br>Try to record the key points: who can authorize disposal and tiered value levels | IF, **NO**, is there an informal/unwritten procedure that is followed?<br><br>Try to record the key points: who can authorize disposal and tiered value levels |
| | F33 | Is there a formal written REGULATION/PROCEDURE for the physical destruction of pharmaceutical items? Yes / No, | |
| | **F34** | **IF YES,** try to determine the source GDPA/MoPH/HLIED, etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime destruction methodology: bury/burn/landfill?<br><br>State method. | **IF, NO**, is there an informal/unwritten procedure that is followed? Yes / No<br><br>If Yes, try to record the prime destruction methodology: bury/burn/landfill<br><br>State method. |

## ANNEX 2: COMPLETED QUESTIONNAIRES

### GENERAL DIRECTORATE FOR PHARMACEUTICAL AFFAIRS
### DATA COLLECTION OF PHARMACEUTICAL ITEMS SCHEDULED FOR DESTRUCTION

**Objectives of the Data Collation of Pharmaceutical Items Scheduled for Destruction**

The MoPH is in the process of formulating an appropriate policy and eventual mechanism for the handling of pharmaceutical items requiring destruction.

In order to better inform and guide the policy development process as to the budgets, range of existing regulations, and the scope of materials and volumes requiring destruction, the GDPA is desirous of collating the information which is currently available on the destruction process and pharmaceutical products scheduled for destruction.

The overall objective is to collate and analyze the data which is available on pharmaceutical destruction processes and the items scheduled for destruction so as to identify any shortfalls in the existing policies and regulations and to formulate estimates of the volume and content of the pharmaceutical items requiring destruction. It is recognized that the current data may be incomplete and can probably be used only for general guidance, but even this can serve a useful purpose.

**Planning Guidance for Data Collectors**

Discuss this briefing note and draft questionnaire with MoPH/GDPA, and seek to actively engage them in the process.

Advise the CPDS of the intended data collation activities and invite any of their members to also complete the proposed questionnaire (on their own) for their own pharmaceutical supply.

Work with MoPH/GDPA staff to determine, which departments are involved in handling data for pharmaceutical items for destruction; where the data is located; and the extent of the data available.

Clearly identify the departments which need to be visited; contact them to confirm that they have data available; and then obtain the necessary permissions to access the available data and work with the Departmental staff.

**Preparations before visiting the Identified Units**

***Notify the Unit of your proposed activities***

Contact the unit(s) explain your proposed activities and provide a copy of the questionnaire. Agree a time to visit the unit and the data collection activities.

**Guidance for Data Collectors – Implementing Questionnaire**

During the visit to the Unit, the Data Compilation Officer(s) should ensure that:

- They take time to explain to the Unit Officer what they are doing and why
- Explain that they are NOT part of an audit team. They are NOT there to measure the performance of the unit—only to collect data to help estimate future volumes.
- The focus of their visit is on the data collection—do not try to make comments or observations on the data at this stage—wait for the analysis
- Unit staff should be treated as equal partners in the search for clarity and resolution; ask for their opinions and inputs.
- If the data is incomplete or confused do NOT try to criticize or even imply criticism—explain to the units staff that we want the best estimate of its accuracy and completeness, so that we can see how it can be used to guide the future policy development

# PHARMACEUTICAL ITEMS FOR DESTRUCTION DATA COMPILATION QUESTIONNAIRE

1. **DATE OF DATA COLLECTION: 20 January 2014**

2. **NAMES OF DATA COLLECTORS: Pharm. Zekria Fatehzada, Pharm. Niamatullah Nawrozian, Pharm. Dawood Shah Waliyar, Pharm. Nazir Hiedarzad, Pharm. Wahidullah Karwar**

3. **NAMES AND TITLES OF PERSONS IN UNIT VISITED: Pharm. Mohammad Naim Yaqubi, Pharmaceutical Establishment Inspection Manager, HLIED Mobile No. 0093799310197**

ADVICE FOR DATA COLLECTORS:

**Data Source:**

It is expected that the two main sources will be GDPA disposal unit and Health legislation and implementation ensuring directorate (HLIED).

For each data source, try to complete a separate, full questionnaire, which follows.

Use one questionnaire for GDPA and another copy for HLIED.

Discuss with the staff involved in processing the disposal/destruction the requests they receive:

How accurate the staff feel the data is—e.g., they think the prices, volumes are reasonable and all departments report—or only a few departments report and they only guess the prices.

Make an estimate of how confident are you with the data to write a report.

| SECTION | | QUESTIONS | | | |
|---|---|---|---|---|---|
| **A WHY are the items scheduled for destruction** | A1 | Try to collect data the volume of the items scheduled for destruction by each reason, by either value (Afghani/USD) or volume (cu m) or by number of line items | | | |
| | A 2 | Is there a system to document the reasons of destruction of the pharmaceuticals? Yes / No. (Although they selected yes, there is not any specific system for documentation of reasons of destruction.) | | | |
| | A 3 | Is there a system to document the reasons and value, volume or line items of the pharmaceuticals for destruction? Yes / No. Same as above. | | | |
| | A4 | Measured by: State: Value, Volume, Line Item count | | | |
| | A5 | Time Period: (e.g., last year) | | | |
| | | **Reason State documented not documented and why not documented** | **Value** | **Volume** | **Line item** |
| | A6 | Date expired | Yes | Yes | Yes |
| | A7 | Damaged | Yes | Yes | Yes |
| | A8 | Failed quality control testing | Yes | Yes | Yes |
| | A9 | Confiscated, unlicensed medicine | Yes | Yes | Yes |
| | A10 | Confiscated prohibited import | Yes | Yes | Yes |
| | A11 | Suspected counterfeit | Yes | Yes | Yes |
| | A12 | Excess to requirements (expired) | Yes | Yes | Yes |
| | A13 | Other substandard | Yes | Yes | Yes |
| | A14 | Other caused specify: | | | |
| **B VOLUME express as cubic meters or metric tons** | | Of the items scheduled for destruction: | | | |
| | B15 | How many line items (individual pharmaceutical preparations items) are present? | | | |
| | | Last 3 months | Last 12 months | | |
| | | | 406 | | |
| | B16 | What is the estimated volume of items for destruction (cubic meters or metric tons) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | 18 tons | | |
| | B17 | Which item represents the largest volume (cubic meters or metric tons) State item: (e.g., paracetamol 500mg) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | Aspirin tablet 500mg, 325mg, 150mg | | |
| | B18 | State volume (cubic meters or metric tons) of the item mentioned above | | | |
| | | Last 3 months | Last 12 months | | |
| | | | 150 Kg | | |
| **C CONTENT** | C19 | Record the volume or weight of **nonmedicine** items (nonmedicine = condoms, gloves, dressings etc.) by volume (cubic meters or weight including packing materials) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | 3.5 tons (approximately) | | |
| | C20 | Record the volume or weight of the pharmaceutical **liquids** (includes syrups, injectable and IV fluids) to solids by volume (cubic meters or weight, e.g., 10% liquids by cubic meters) | | | |
| | | Last 3 months | Last 12 months | | |
| | | | Unknown | | |
| | C21 | Are there any antineoplastic/cytotoxic preparations present? Yes / No | | | |
| | | Last 3 months | Last 12 months | | |
| | | | | | |
| | C22 | Are there any hormonal contraceptives present? Yes / No | | | |
| | | Last 3 months | Last 12 months | | |
| | | | Depo Provera (100 Vials) | | |
| | C23 | Are there any Fixed-Dose Combination (FDC) preparations for TB, | | | |

| SECTION | | QUESTIONS | |
|---|---|---|---|
| | | malaria, or HIV present? Yes / No | |
| | | Last 3 months | Last 12 months |
| | | | |
| **D COSTS express as Afghani or USD** | D24 | What is the estimated value of items for destruction (Afghani or USD)? | |
| | | Last 3 months | Last 12 months |
| | | | USD 44,830 |
| | D25 | Which one pharmaceutical line item represents the largest cost? state item | |
| | | Last 3 months | Last 12 months |
| | | | Tablet Aspirin |
| | D26 | State value of this one largest item (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | | USD 4,070 |
| | D27 | What is the total cost of the nonmedicine items present? (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | | USD 4,690 |
| | D28 | What is the largest source by cost of the items? e.g., USAID, CMS, UNFPA, etc. | |
| | | Last 3 months | Last 12 months |
| | | | Private Sector |
| **E Existing Policy for write-off, disposal, and destruction of pharmaceutical products** | E29 | Is there a formal written **POLICY f**or the **write-off, disposal** of pharmaceutical items? Yes / No<br><br>If Yes, try to determine the source: GDPA/MoPH/HLIED, etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>If a copy is not available try to record key points<br><br>• who can authorize<br>• number of authorities (signatures) required<br>• value limits<br>• Single value limit and what is the value:<br>• Multiple tiered values:<br>• Tier 1 value and number of signatures required:<br>• Tier 2 value and number of signatures required:<br>• Tier 3 value and number of signatures required: | |
| | E30 | Is there a formal written **POLICY for the physical destruction** of pharmaceutical items? Yes / No<br><br>If Yes, try to determine the source GDPA/MoPH/HLIED, etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime disposal methodology: bury/burn/landfill<br><br>State method. | |

| SECTION | | QUESTIONS | |
|---|---|---|---|
| **F Existing regulations for WODA (write-off, disposal, and destruction) of pharmaceutical products** | F31 | Is there a formal written REGULATION/PROCEDURE for the write-off, disposal of pharmaceutical items. Yes / No. There is 2 or 3 articles in the medicines law and the MoPH newly approved a Bill (Lyha) for destruction of pharmaceutical wastes. | |
| | F32 | IF **YES**, try to determine the source: GDPA/MoPH/HLIED, etc.<br>State source:<br><br>and try to obtain a copy of the document<br><br>IF a copy is not available<br><br>Try to record the key points: who can authorize disposal and tiered value levels | IF **NO**, is there an informal/unwritten procedure that is followed?<br><br>Try to record the key points: who can authorize disposal and tiered value levels |
| | F33 | Is there a formal written REGULATION/PROCEDURE for the physical destruction of pharmaceutical items? Yes / No. Just it is indicated in the medicines law that the pharmaceutical wastes should be destroyed based on the WHO guideline. | |
| | **F34** | **IF YES,** try to determine the source GDPA/MoPH/ HLIED, etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime destruction methodology: bury/burn/landfill<br><br>State method. | **IF NO**, is there an informal/unwritten procedure that is followed? Yes / No<br><br>If yes, Try to record the prime destruction methodology: bury/burn/landfill<br><br>State method. |

## Upon Completion of the Data Collections

Thank the unit for their cooperation.
Advise GDPA that you have completed the data collection process.
Pass the competed questionnaires to SPS/SIAPS for analysis.

END

# GENERAL DIRECTORATE FOR PHARMACEUTICAL AFFAIRS
# DATA COLLECTION OF PHARMACEUTICAL ITEMS SCHEDULED FOR DESTRUCTION

## Objectives of the Data Collation of Pharmaceutical Items Scheduled for Destruction

The MoPH is in the process of formulating an appropriate policy and eventual mechanism for the handling of pharmaceutical items requiring destruction.

In order to better inform and guide the policy development process as to the budgets, range of existing regulations, and the scope of materials and volumes requiring destruction, the GDPA is desirous of collating the information which is currently available on the destruction process and pharmaceutical products scheduled for destruction.

The overall objective is to collate and analyze the data which is available on pharmaceutical destruction processes and the items scheduled for destruction so as to identify any shortfalls in the existing policies and regulations and to formulate estimates of the volume and content of the pharmaceutical items requiring destruction. It is recognized that the current data may be incomplete and can probably be used only for general guidance, but even this can serve a useful purpose.

## Planning Guidance for Data Collectors

Discuss this briefing note and draft questionnaire with the MoPH/GDPA, and seek to actively engage them in the process.

Advise the CPDS of the intended data collation activities and invite any of their members to also complete the proposed questionnaire (on their own) for their own pharmaceutical supply.

Work with MoPH/GDPA staff to determine, which departments are involved in handling data for pharmaceutical items for destruction; where the data is located; and the extent of the data available.

Clearly identify the departments which need to be visited; contact them to confirm that they have data available; and then obtain the necessary permissions to access the available data and work with the departmental staff.

## Preparations before visiting the Identified Units

### *Notify the Unit of your proposed activities*

Contact the unit(s) explains your proposed activities and provides a copy of the questionnaire.

Agree a time to visit the unit and the data collection activities.

## Guidance for Data Collectors – Implementing Questionnaire

During the visit to the Unit, the Data Compilation Officer(s) should ensure that:

- They take time to explain to the Unit Officer what they are doing and why.
- Explain that they are NOT part of an audit team. They are NOT there to measure the performance of the unit—only to collect data to help estimate future volumes.
- The focus of their visit is on the data collection—do not try to make comments or observations on the data at this stage—wait for the analysis.
- Unit staff should be treated as equal partners in the search for clarity and resolution; ask for their opinions and inputs.
- If the data are incomplete or confused do NOT try to criticize or even imply criticism—explain to the units staff that we want the best estimate of its accuracy and completeness, so that we can see how it can be used to guide the future policy development.

## PHARMACEUTICAL ITEMS FOR DESTRUCTION DATA COMPILATION QUESTIONNAIRE

1. **DATE OF DATA COLLECTION: 24, 28 September and 2 October 2013**

2. **NAMES OF DATA COLLECTORS: Pharm. Zekria Fatehzada, Pharm. Niamatullah Nawrozian, Pharm. Dawood Shah Waliyar, Pharm. Nazir Hiedarzad, Pharm. Wahidullah Karwar**

3. **NAMES AND TITLES OF PERSONS IN UNIT VISITED: Pharm. Zekria Fatehzada, GDPA monitoring (local production and import companies) Manager**

ADVICE FOR DATA COLLECTORS:

**Data Source:**

It is expected that the two main sources will be GDPA disposal unit and Health legislation and implementation ensuring directorate (HLIED).

For each data source, try to complete a separate, full questionnaire, which follows.

Use one questionnaire for GDPA and another copy for HLIED.

Discuss with the staff involved in processing the disposal/destruction the requests they receive:

How accurate the staff feel the data is—e.g., they think the prices, volumes are reasonable and all departments report—or only a few departments report and they only guess the prices.

Make an estimate of how confident are you with the data to write a report.

| SECTION | | QUESTIONS | | | |
|---|---|---|---|---|---|
| **A WHY are the items scheduled for destruction** | A1 | Try to collect data the volume of the items scheduled for destruction by each reason, by either value (Afghani/USD) or volume (cu m) or by number of line items | | | |
| | A 2 | Is there a system to document the reasons of destruction of the pharmaceuticals? Yes / No (Although there is not any specific system, documents are available and not in a systematic manner). | | | |
| | A 3 | Is there a system to document the reasons and value, volume or line items of the pharmaceuticals for destruction? Yes / No (The value is not calculated or estimated; sometimes the volume is estimated, but there is not any specific system to calculate or estimate the volume.) | | | |
| | A4 | Measured by: State: Value, Volume, Line Item count | | | |
| | A5 | Time Period: (e.g., last year) | | | |
| | | **Reason**<br><br>**State documented not documented and why not documented.** There is not any specific method to calculate/measure the volume of the waste pharmaceuticals. But during the destruction time, the assigned destruction team will roughly determine the value of the waste medicines. | **Value** | **Volume** | **Line Item** |
| | A6 | Date expired | N/A | N/A | Yes |
| | A7 | Damaged | N/A | N/A | Yes |
| | A8 | Failed quality control testing | Yes | Yes | Yes |
| | A9 | Confiscated, unlicensed medicine | N/A | Yes | Yes |
| | A10 | Confiscated prohibited import | N/A | Yes | Yes |
| | A11 | Suspected counterfeit | N/A | Yes | Yes |
| | A12 | Excess to requirements (expired) | N/A | N/A | N/A |
| | A13 | Other substandard | N/A | Yes | Yes |
| | A14 | Other caused specify: | N/A | N/A | N/A |
| | | | | | |
| **B VOLUME express as cu m or metric tons** | | Of the items scheduled for destruction: | | | |
| | B15 | How many line items (individual pharmaceutical preparations items) are present? | | | |
| | | Last 3 months | Last 12 months | | |
| | | N/A | The 109 items of medicines already sent to GDPA by different public and private sector agencies, but physically the items are not available in the GDPA. The GDPA will collect all these items after the MoPH approval. | | |
| | B16 | What is the estimated volume of items for destruction (cubic meters or tons) | | | |
| | | Last 3 months | Last 12 months | | |
| | | N/A | N/A The volume is calculated at the time when all the items received from different agencies. | | |
| | B17 | Which item represents the largest volume (cubic meters or tons)<br>State Item: (e.g. paracetamol 500 mg) | | | |
| | | Last 3 months | Last 12 months | | |
| | | N/A | N/A | | |
| | B18 | State volume (cubic meters or tons) of the item mentioned above. The volume will be calculated/estimated after collecting of all items. But there is not any mechanism to identify the largest volume (cubic meters or tons) of individual items during destruction. | | | |
| | | Last 3 months | Last 12 months | | |
| | | N/A | N/A | | |
| | | | | | |

| CATEGORY | | QUESTIONS | |
|---|---|---|---|
| **C CONTENT** | C19 | Record the volume or weight of **nonmedicine** items (nonmedicine = condoms, gloves, dressings, etc.) by volume (cubic meters or weight including packing materials) | |
| | | Last 3 months | Last 12 months |
| | | N/A | N/A |
| | C20 | Record the volume or weight of the pharmaceutical **liquids** (includes syrups, injectable and IV fluids) to solids by volume (cubic meters or weight, e.g., 10% liquids by cubic meters) | |
| | | Last 3 months | Last 12 months |
| | | N/A | N/A |
| | C21 | Are there any antineoplastic/cytotoxic preparations present? Yes / No | |
| | | Last 3 months | last 12 months |
| | | | |
| | C22 | Are there any hormonal contraceptives present? Yes / No | |
| | | Last 3 months | Last 12 months |
| | | | |
| | C23 | Are there any Fixed-Dose Combination (FDC) preparations for TB, malaria, or HIV present? Yes / No | |
| | | Last 3 months | Last 12 months |
| | | | |
| **D COSTS express as Afghani or USD** | D24 | What is the estimated value of items for destruction? (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | N/A | USD 6,000 |
| | D25 | Which one pharmaceutical line item represents the largest cost? state item The estimated value is only for imported medicines which failed QC test in Kabul (the samples were collected from Kabul customs). There are substandard medicines from other provinces, e.g., Nangarhar, Kandahar, Herat, not included. | |
| | | Last 3 months | Last 12 months |
| | | N/A | Syrup- Paracetamol |
| | D26 | State value of this one largest item (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | N/A | USD 1,280 |
| | D27 | What is the total cost of the nonmedicine items present? (Afghani or USD) | |
| | | Last 3 months | Last 12 months |
| | | N/A | N/A |
| | D28 | What is the largest source by cost of the items? e.g., USAID, CMS, UNFPA, etc. | |
| | | Last 3 months | Last 12 months |
| | | N/A | N/A |
| **E Existing Policy for write-off disposal and destruction of pharmaceutical products** | E29 | Is there a formal written **POLICY f**or the **write-off disposal** of pharmaceutical items? Yes / No<br><br>If Yes, try to determine the source: GDPA/MoPH/HLIED etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>If a copy is not available try to record key points<br>• who can authorize<br>• number of authorities (signatures) required<br>• value limits<br>• Single value limit and what is the value:<br>• Multiple tiered values:<br>• Tier 1 value and number of signatures required:<br>• Tier 2 value and number of signatures required:<br>• Tier 3 value and number of signatures required: | |

| | | | |
|---|---|---|---|
| | E30 | Is there a formal written **POLICY for the physical destruction** of pharmaceutical items? Yes / No<br><br>If Yes, try to determine the source GDPA/MoPH/HLIED etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime disposal methodology: bury/burn/landfill<br>State method. | |
| **F<br>Existing regulations for WODA (write-off, disposal, and destruction) of pharmaceutical products** | F31 | Is there a formal written REGULATION/PROCEDURE for the write-off disposal of pharmaceutical items. Yes / No. There is 2 or 3 articles in the medicines law and the MoPH new approved a Bill (Lyha) for destruction pharmaceutical wastes. | |
| | F32 | IF **YES**, try to determine the source: GDPA/MoPH/HLIED etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>IF a copy is not available<br><br>Try to record the key points – who can authorize disposal, and tiered value levels | IF **NO**, is there an informal/unwritten procedure that is followed?<br><br>Try to record the key points – who can authorize disposal, and tiered value levels |
| | F33 | Is there a formal written REGULATION/PROCEDURE for the physical destruction of pharmaceutical items? Yes / No. Just it is indicated in the medicines law that the pharmaceutical wastes should be destroyed based on the WHO guideline. | |
| | **F34** | **IF YES,** try to determine the source GDPA/MoPH/HLIED etc.<br><br>State source:<br><br>and try to obtain a copy of the document<br><br>What is the prime destruction methodology: bury/burn/landfill<br><br>State method. Most of the pharmaceutical wastes are burned, and just for one time they used the encapsulation method for few items. | **IF, NO**, is there an informal/unwritten procedure which is followed? Yes / No<br><br>If yes, Try to record the prime destruction methodology: bury/burn/landfill<br><br>State method. |

## Upon Completion of the Data Collections

Thank the unit for their cooperation.

Advise GDPA that you have completed the data collection process.

Pass the competed questionnaires to SPS/SIAPS for analysis.

END



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